

Exhibit 1

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

THE UNITED STATES OF AMERICA *et al.*
ex rel. JULIE LONG,

Plaintiffs,

V.

JANSSEN BIOTECH, INC.,

Defendant.

Civil Action No.
16-12182-FDS

**PLAINTIFF’S FOURTH SUPPLEMENTAL OBJECTIONS
AND RESPONSE TO DEFENDANT’S INTERROGATORY NO. 2**

Pursuant to Federal Rules of Civil Procedure 26 and 33 and Local Civil Rule 33.1, plaintiff-relator Julie Long (“Plaintiff”) hereby submits the below supplemental objections and response to defendant Janssen Biotech, Inc.’s (“Defendant”) Interrogatory No. 2 (hereinafter, the “Interrogatory”), as follows:

PRELIMINARY STATEMENT

The information contained in the response set forth below is based upon information and documents currently available to Plaintiff. Plaintiff's investigation and discovery in this matter is not complete. Additional investigation and discovery may provide further information and documents relevant to this response, as could information and documents obtained from Defendant and/or third parties through additional discovery procedures. The below response is based upon information known at the time and is given without prejudice to Plaintiff's right to supplement the response prior to trial or to produce evidence based on subsequently discovered information. Plaintiff's response is based upon, and therefore limited by, Plaintiff's present

knowledge and, consequently, Plaintiff reserves the right to revise, amend, or supplement the response as appropriate.

Plaintiff's response to all or any part of the Interrogatory should not be taken as an admission that: (1) Plaintiff accepts or admits the existence of any fact set forth in or assumed by the Interrogatory; (2) Plaintiff has in her possession, custody, or control documents responsive to that Interrogatory; or (3) documents responsive to that Interrogatory exist. Plaintiff reserves the right to contest Defendant's characterization of any facts, circumstances, or legal obligations as inaccurate.

Plaintiff's response to all or any part of the Interrogatory is not intended to be, and shall not be, a waiver by Plaintiff of all or any part of her objection(s) to the Interrogatory.

GENERAL OBJECTIONS

Plaintiff incorporates the following general objections into the response set forth below. Plaintiff does not waive any of these general objections in her response to the Interrogatory. Any specific objection made by Plaintiff in no respect limits or modifies these general objections. Plaintiff's objections and response are made without waiving or intending to waive, but rather intending to preserve and preserving: (1) all objections to competency, relevance, materiality, privilege, and admissibility as evidence for any purpose in this proceeding; (2) the right to object to, on any ground, any demand for further response to this or any other discovery requests; (3) the right to preserve, prior to providing and as a condition of providing, the confidentiality of any information that may be provided or the subject matter thereof; (4) the right at any time to revise, supplement, clarify, or amend the response and objections to the Interrogatory, if further factual developments or analysis warrants a modification, or if additional information is obtained or

documents are located that are properly called for by the Interrogatory; and (5) all rights existing at the time of this response.

Plaintiff's specific objections to the Interrogatory are in addition to the general limitations and objections set forth in this section. These limitations and objections form a part of the response to the Interrogatory and are set forth here to avoid the duplication and repetition of restating them for the response. The absence of a reference to a general objection should not be construed as a waiver of the general objection as to the Interrogatory.

1. Plaintiff objects to the Interrogatory to the extent that the definitions and instructions seek to impose obligations beyond those required by the Federal Rules of Civil Procedure, Local Civil Rules, or Orders of this Court, or require production of materials or information prohibited by law. Plaintiff will comply with the requirements set forth in the Federal Rules of Civil Procedure, Local Civil Rules, and Orders of this Court, but will not comply with any definition or instruction that seeks to impose a greater requirement.

2. Plaintiff objects to the Interrogatory to the extent that it seeks information: (a) that is protected from discovery pursuant to the attorney-client privilege, attorney work product doctrine, common-interest privilege, joint prosecutorial privilege, or any other applicable privilege, protection, immunity, or limitation on discovery; (b) that was prepared in anticipation of litigation; or (c) that is otherwise protected from disclosure under the Federal Rules, relevant federal procedural rules, or relevant case law. No information covered by any privilege, protection, immunity, or limitation will be intentionally disclosed. In the event that any such information is disclosed by Plaintiff, such disclosure is inadvertent and does not constitute a waiver of any privilege, protection, immunity, or limitation from disclosure. Plaintiff reserves the

right to demand the return of any privileged or otherwise protected information inadvertently produced during discovery.

3. Plaintiff objects to the Interrogatory to the extent that it purports to require information or production of documents concerning any expert or other person or entity retained by Plaintiff's counsel to assist in the preparation of Plaintiff's case but who will not be designated by Plaintiff as an affiant or witness on the grounds that such disclosure violates the attorney work-product doctrine and is not required by the Federal Rules of Civil Procedure.

4. Plaintiff objects to the Interrogatory to the extent that it seeks legal conclusions and/or ultimate factual determinations.

5. Plaintiff objects to the Interrogatory to the extent that it seeks information, documents, or other materials that are within the possession, custody, or control of Defendant, and/or its counsel, and/or that are publicly available, and, therefore, may be accessed by Defendant with less burden than Plaintiff can identify and provide the requested information. In particular, the Interrogatory purports to require Plaintiff to replicate information already provided by Plaintiff to Defendant through the pleadings and during the course of discovery in this action.

6. Plaintiff objects to the Interrogatory to the extent that it seeks information not within the possession, custody, or control of Plaintiff, or that are available from a more convenient, more efficient, less burdensome, or less expensive source. Plaintiff's search and response will be limited to information reasonably in her possession, custody or control.

7. Plaintiff objects to the Interrogatory to the extent that it is not proportional to the needs of the case.

8. Plaintiff objects to the Interrogatory to the extent that it seeks information that is not relevant to the claims or defenses of any party to this action, nor reasonably calculated to

lead to the discovery of admissible evidence under the Federal Rules or otherwise purport to impose any obligation on Plaintiff beyond that required or permitted by the Federal Rules or the Local Rules, or other rules or practices applicable to cases in this Court.

9. Plaintiff objects to the Interrogatory to the extent that it is overbroad or seeks irrelevant information and is therefore unduly burdensome.

10. Plaintiff objects to the Interrogatory to the extent that it is vague or ambiguous and, as such, would require Plaintiff to speculate as to the meaning of the Interrogatory.

11. Plaintiff objects to the Interrogatory to the extent that it prematurely seeks information that is required to be disclosed in a pre-trial order, such as the identity of testifying witnesses or exhibits to be used at trial.

12. Plaintiff objects to the Interrogatory to the extent that it seeks information that is duplicative, cumulative, and/or redundant of Defendant's requests for the production of documents or other discovery sought or provided in this action.

13. Plaintiff objects to the Interrogatory to the extent that it is compound and contains multiple numbered and unnumbered subparts.

14. Plaintiff objects to the Interrogatory to the extent that Defendant asserts Plaintiff's response thereto constitutes an adoption or acceptance of terms or definitions that Defendant has employed, including to the extent that it seeks to define terms and/or characterize the evidence or pleadings in this matter. In responding to the Interrogatory, Plaintiff does not adopt, embrace, or accept any term or definition employed by Defendant. To the extent that Plaintiff adopts any terms used by Defendant in the Interrogatory, such adoption is specifically limited to this response and shall not be construed as an admission. This response is made based upon

Plaintiff's interpretation of words contained in the Interrogatory, unless a specific definition or instruction has been agreed upon.

15. Plaintiff objects to the Interrogatory to the extent that it misstates, misdescribes, or misconstrues Plaintiff's claims or allegations.

16. In submitting this response, Plaintiff expressly reserves the right to object on any ground whatsoever to the use as evidence or any other use of the information provided in this or any other proceeding.

17. Plaintiff objects to the extent the Defendant's Interrogatory is directed to counsel.

18. Plaintiff objects to the Interrogatory to the extent that it seeks to impose additional and/or different discovery obligations than those discovery obligations imposed pursuant to any orders entered by the Court and/or any agreements between the Parties regarding the discovery of electronically stored information and/or confidential information.

19. Plaintiff's response is not an admission or agreement that the request is proper or a waiver of an objection, should an interrogatory be made for further similar information.

OBJECTIONS AND RESPONSE

INTERROGATORY 2: Identify all services provided by You or Defendant and any Physicians or Physician Practices that You allege violate the AKS or FCA, including but not limited to any meetings, presentations, communications, or other interactions between You or Defendant and any Physicians or Physician Practices.

RESPONSE TO INTERROGATORY 2:

Plaintiff objects to this Interrogatory as improper, overbroad and unduly burdensome on the grounds that it requests identification of "all" services, meetings, presentations, communications and interactions that violated the Anti-Kickback Statute. Plaintiff also objects

on the ground that this contention interrogatory is premature. Plaintiff also objects on the ground that this Interrogatory seeks information already in Defendant's possession and is therefore unnecessarily burdensome. Plaintiff will rely upon information and documents in the possession custody and control of Defendant, which Plaintiff has requested but Defendant has not yet fully produced or disclosed. Plaintiff further reserves the right to amend or supplement this Response, including by way of pre-trial disclosures.

Subject to the foregoing objections and general objections, Plaintiff responds as follows: Advisory, educational, and consultative assistance, support, and services concerning the topics listed below (hereinafter, collectively referred to as the "Services") that Defendant provided (directly through Area Business Specialists or through outside consultants (such as Xcenda, The Lash Group, The Resource Group, and Akin Gump)), under national directives, to the Phase 1 Accounts (defined below) as well as other selected or targeted physician practices that are identified in documents Defendant produced, constituted illegal remuneration, the provision of which violated the Anti-Kickback Statute:

- (1) establishing and opening an initial IOI (defined below)
- (2) opening an IOI at another location
- (3) the practice's readiness for administering infusions in a new IOI
- (4) the optimal design, furniture, and décor of the IOI
- (5) using a gastroenterology practice's ambulatory surgical center as an IOI (reclassifying ASC space to office space to allow for provision of infusion services in compliance with Medicare requirements)
- (6) identifying and addressing a practice's IOI's operational needs and challenges
- (7) enhancements to the IOI that would increase patient satisfaction (to attract more patients and enable the practices to negotiate higher reimbursement rates from private payers and patients)

- (8) the infusion business model
- (9) growing or maintaining the IOI
- (10) the assessment and evaluation of the IOI's infusion procedure volume and capacity
- (11) adding other infusion service lines or treatments to an IOI
- (12) making other physicians, who do not perform infusions in their offices, aware of the practice's IOI and seeking referral arrangements with such physicians
- (13) operating IOIs more efficiently and profitably (and lowering overhead costs)
- (14) optimizing the infusion schedule (maximizing infusion procedures and minimizing staffing time and costs)
- (15) establishing and implementing standard operating procedures to improve the IOI workflow and billing processes
- (16) management of the inventory of infusible drugs and infusion procedure supplies
- (17) acquisition of drugs administered in the IOI
- (18) management of the financial risks related to infusing drugs in the IOI
- (19) tracking accounts receivable and payments from payers and patients for infusion drugs and services
- (20) obtaining coverage exceptions and overturning payment denials through appeals
- (21) private payer coverage and reimbursement trends
- (22) best contracting practices and management of relationships with private payers and the government health care programs
- (23) negotiating higher reimbursement rates from private payers for frequently billed services and drugs (starting with benchmarking and evaluating existing terms of contracts with private payers and reimbursement rates)
- (24) government legislative and policy changes, programs, and trends that impact physician practices
- (25) avoiding and responding to an audit of the practice's claims for payment by Medicare

- (26) qualifying for incentive payments and avoiding penalties under the Health Information Technology for Economic and Clinical Health (HITECH) Act and Medicare's Electronic Health Record Incentive Program (including achieving meaningful use criteria with electronic health records)
- (27) qualifying for incentive payments under Medicare's Electronic-Prescribing (eRx) Incentive Program
- (28) qualifying for the incentive payments and payment adjustments under CMS's Physician Quality Reporting System (PQRS)
- (29) qualifying for the incentive payments under Medicare's Merit-Based Incentive Payment System
- (30) preparing the practice for conversion to the ICD-10 coding system

With the exception of advice and assistance provided concerning opening an initial IOI and opening an IOI at another location (items 1-3 above), the Services listed above were normally provided to the selected and targeted practices through consultative meetings, which were also commonly referred to as, among other names, "programs" and "presentations," that were presented by Area Business Specialists (in-person) or by outside consultants (in-person, by teleconference, or by videoconference) (hereinafter, the "presentations and programs"), including the presentations and programs identified below (and their substantive equivalents)¹:

- (1) Becoming an Alternative Site of Care for Therapy with Remicade in Your Community
- (2) Billing and Coding for Infusions
- (3) Checkpoints for Infusion Center Optimization
- (4) Considerations for Proactive Practice Management (a/k/a Current Considerations for Proactive Practice Management; Proactive Practice Management)
- (5) Considerations for Standard Operating Procedures in the Infusion Suite

¹ In this action, Plaintiff has used the terms "Infusion Business Support" and "IOI Support" to collectively refer to the Services and the related presentations and programs through which Services were provided.

- (6) Considerations for Working with a Specialty Pharmacy (a/k/a Specialty Pharmacy Considerations)
- (7) Electronic Health Records and Meaningful Use (Part 1 and Part 2)
- (8) Emerging Trends in Health Care
- (9) Enhancing Patient Care and Access
- (10) Exceptions and Appeals
- (11) ICD-10
- (12) In-Office Infusion Drug Procurement Models
- (13) Infusion Business Review (a/k/a iBiz)
- (14) Infusion Optimization Modeler (a/k/a IOM)
- (15) Infusion Referrals: Improving the Continuity of Care (a/k/a Coordinating the Continuity of Care with Infusion Referrals; Quality Improvements in Coordinating the Continuity of Care with Infusion Referrals)
- (16) Infusion Services Review
- (17) Infusion Suite Scheduling and Staffing
- (18) Infusion Therapy Services Provided in Converted ASC Space (a/k/a Infusion Services and Ambulatory Surgical Centers (ASCs) – Planning Considerations; ASC Space Reclassification for Infusion Therapy)
- (19) Inventory and Supply Management
- (20) IV Therapy: An Important Option for Your Patients (a/k/a Why IV)
- (21) Managing Biologics in the Physician Office (a/k/a MBPO)
- (22) Medicare Audits
- (23) *Medicare Quality Payment Program: A Focus on MIPS
- (24) *Patient Experience in the Infusion Suite
- (25) Payer Relationship Management
- (26) Practice Compliance for Remicade

- (27) Private Payer Contracting Considerations (Part 1 and Part 2) (a/k/a Private Payer Contracting Considerations for Therapy with Remicade)
- (28) Quality of Care in the Infusion Suite
- (29) Raising the Infusion Suite Experience (a/k/a RISE)
- (30) Remicade Account Review (a/k/a Physician Office Account Review for Remicade)
- (31) Setting Up In-Office Infusions of Remicade: Informational Resources
- (32) *Specialty Drug Market Dynamics: Implications for Infusions
- (33) Successful Implementation of a New Infusion Suite
- (34) Successful Implementation of a New Infusion Suite for Gastroenterology Practices
- (35) Successful Infusion Site Management for Gastroenterology (a/k/a Successful Infusion Suite Management for Gastroenterology)
- (36) Akin Gump teleconferences, including, but not limited to: (a) Medicare Physician Payment Update; (b) Healthcare Reform Update; and (c) Medicare Shared Savings Program and Accountable Care Organization Proposed Rule Update

(The presentations and programs that are preceded by an asterisk may have become available for use and furnished by Defendant (directly through Area Business Specialists or through outside consultants) after Plaintiff left Defendant). As part of the presentations and programs, Defendant typically had the Area Business Specialists and outside consultants use slide decks as visual aids (presented on the Area Business Specialist's electronic device or projected on a screen) and, for some presentations and programs, customized infusion schedule optimization models and other materials to assist with and facilitate the provision of the Services. Plaintiff, and she believes other Area Business Specialists, provided certain Services and the related presentations and programs over multiple days or sessions. Additionally, as part of Defendant's provision of many Services and related presentations and programs, the Area Business Specialists monitored the

physician practices' progress in implementing the advice and recommended changes and, when needed, provided further consultation on the topic or issue.

Dates when Defendant provided the Services (and related presentations and programs) identified above are reported in Defendant's and outside consultants' reports (*e.g.*, RBM Report, MBPO Tracker, Monthly Report, ABS Business Plan, MBO Reports, Programming Analysis Reports, SOC Report, SOC 360 Programs Report, SOC Speaker Program Tracker, SOC Dashboard, Account Action Reports, and Budget Reconciliation Reports) and Defendant's data systems (*e.g.*, iConnect, ViewPoint, IAM (a/k/a Red Rover), and SharePoint). The below list of documents produced by Defendant or Xcenda, as well as Defendant's response to Interrogatory 18 and the letters from Defendant's counsel dated August 11, 2021 and October 7, 2022 (Exhibit A to the letter) report some of the dates or time periods when Defendant provided the Services and related presentations and programs to the Phase 1 Accounts as well as physician practices in other territories. Plaintiff has requested that Defendant produce documents and information reporting additional dates when the company (through Area Business Specialists or through outside consultants) provided the Services and related presentations and programs identified above to the Phase 1 Accounts. Other documents and information that Defendant has produced to Plaintiff, as well as documents and information that Plaintiff has produced to Defendant (*see, e.g.*, Plaintiff's response to Interrogatory 6), further evidence the offering or provision of the Services and related presentations and programs to Phase 1 Accounts. Additionally, under Defendant's practices and policies, many of the Services and related presentations and programs that Defendant provided (directly through Area Business Specialists and indirectly through outside consultants) to physician practices were not specifically tracked or recorded.

JANSSEN.008.0128874
JANSSEN.009.0000778

JANSSEN.009.0242094
JANSSEN.011.0017999

JANSSEN.011.0025272
JANSSEN.011.0050093

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JANSSEN.012.0142923	JANSSENBIO-011-00000750	JANSSENBIO-014-00002702
JANSSEN.012.0235679	JANSSENBIO-011-00003090	JANSSENBIO-014-00004067
JANSSEN.012.0275619	JANSSENBIO-011-00003091	JANSSENBIO-014-00004074
JANSSEN.013.0281531	JANSSENBIO-011-00004096	JANSSENBIO-017-00002508
JANSSEN.013.0322260	JANSSENBIO-011-00004659	JANSSENBIO-017-00004137
JANSSEN.017.0201760	JANSSENBIO-011-00007242	JANSSENBIO-017-00007438
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JANSSENBIO-005-00000047	JANSSENBIO-011-00011678	JANSSENBIO-019-00000083
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JANSSENBIO-005-00000051	JANSSENBIO-011-00012521	JANSSENBIO-019-00001936
JANSSENBIO-005-00001454	JANSSENBIO-012-00000131	JANSSENBIO-019-00002478
JANSSENBIO-007-00000801	JANSSENBIO-012-00005378	JANSSENBIO-021-00001419
JANSSENBIO-007-00000819	JANSSENBIO-012-00005893	JANSSENBIO-021-00001446
JANSSENBIO-007-00000863	JANSSENBIO-012-00006708	JANSSENBIO-021-00004808
JANSSENBIO-007-00001506	JANSSENBIO-012-00007326	JANSSENBIO-045-00001335
JANSSENBIO-007-00001869	JANSSENBIO-012-00007942	JANSSENBIO-045-00001336
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JANSSENBIO-008-00004607	JANSSENBIO-013-00004966	XCE-CID0006392
JANSSENBIO-008-00005415	JANSSENBIO-013-00005042	XCE-CID0006584
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JANSSENBIO-009-00010625	JANSSENBIO-013-00009666	XCE-CID0027679
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JANSSENBIO-009-00010637	JANSSENBIO-013-00010820	XCE-CID0028430
JANSSENBIO-009-00010643	JANSSENBIO-013-00010884	Production 35 Appendix
JANSSENBIO-010-00000638	JANSSENBIO-013-00010923	

“Phase 1 Accounts” refers collectively to the following physician practices, including the physician practices’ owners, shareholders, partners, limited partners, employees, subsidiaries, affiliates, predecessors, and successors:

- (1) Altoona Arthritis & Osteoporosis Center
- (2) Arthritis & Osteoporosis Center
- (3) Berks Center for Digestive Health (a/k/a Berks Center for Digestive Disease; Digestive Disease Associates; Digestive Disease of West Reading (DDWR))
- (4) Capital Arthritis and Rheumatology Associates (f/k/a George Kunkel, M.D.)
- (5) Cumberland Valley Rheumatology (f/k/a Schlansky & Clawson)
- (6) Ellen M. Field-Rubbo, M.D.
- (7) Emkey Arthritis & Osteoporosis Clinic
- (8) Jackson Siegelbaum Gastroenterology (f/k/a West Shore Endoscopy Center)
- (9) Pottstown Medical Specialists (a/k/a PMSI)
- (10) Sanford, Roumm, and Acharya Rheumatology (f/k/a Sanford and Roumm Rheumatology)
- (11) U.S. Digestive Health (f/k/a Lancaster Gastroenterology (LGI))
- (12) U.S. Digestive Health (f/k/a Regional Gastroenterology Associates of Lancaster (RGAL))

“IOI” means an in-office infusion suite or infusion business operated by a physician-owned rheumatology or gastroenterology practice.

DATED: June 6, 2023

/s/ Casey M. Preston

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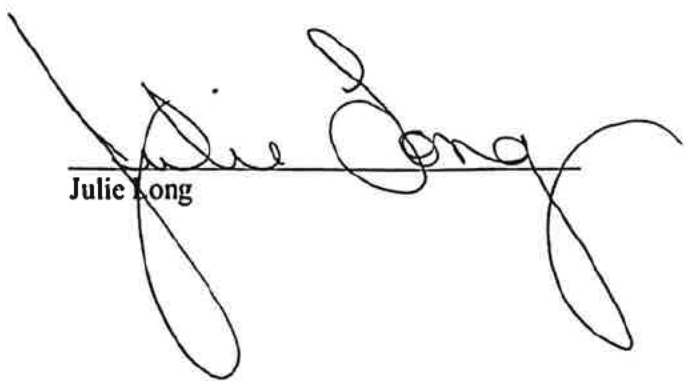
Counsel for Plaintiff-Relator Julie Long

VERIFICATION

I am the plaintiff-relator in this action and have reviewed the foregoing supplemental response to Defendant's Interrogatory No. 2.

I verify under penalty of perjury that the factual statements contained in the foregoing supplemental response to Defendant's Interrogatory No. 2 are true and correct to the best of my knowledge, information, and belief.

Executed on June 5, 2023


Julie Long

CERTIFICATE OF SERVICE

I hereby certify that on June 6, 2023, a copy of the foregoing Plaintiff's Fourth Supplemental Objections and Response to Defendant's Interrogatory No. 2 was served electronically on the following counsel:

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